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510(k) Summary

MedRelief Microcurrent TENS

Common/Classification Name: TENS Device, 21 CFR 882.5890

Healthonics, Inc.
1359 Silver Bluff Road, Suite G-6
Aiken, SC 29803

Contact: James W. Kronberg
Prepared: November 7, 2000

A. LEGALLY MARKETED PREDICATE DEVICES

The MedRelief Microcurrent TENS device is substantially equivalent to the MONAD Freedom Micro Pro microcurrent stimulator (K904430), a single-mode microcurrent device, and also to the Advance Medequip Micro 850 Microcurrent Device (510(k) number not known, but presently marketed in the U.S.), also a single-mode microcurrent device.

B. DEVICE DESCRIPTION

The MedRelief stimulator is completely powered by a 9-volt battery. It has no provision for line power or an AC adaptor. The stimulator produces microcurrent pulse trains separated by intervals of no signal. There are three modulation settings and three amplitude settings.

Each pulse train consists of a series of biphasic, quasirectangular pulses. Each bi-phasic pulse is made up of a primary pulse of 200-1200 microseconds duration, followed by a secondary pulse of opposite polarity and of 30-170 microseconds duration. Each pulse train has 6-50 pulses, followed by a balancing pulse of about 3 ms duration to reduce the net DC current to zero. The pulse train is about 10 milliseconds long and is repeated each 67 milliseconds. Each timing interval is accurate to plus or minus 10% or 10 microseconds, whichever is greater.

C. INTENDED USE

The MedRelief Microcurrent TENS device is indicated for the relief of chronic intractable pain.

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D. SUBSTANTIAL EQUIVALENCE SUMMARY

The MedRelief Microcurrent TENS is a medical device, and it has the same indications for use and target population as the legally marketed predicate devices. The MedRelief Microcurrent TENS has the same technological characteristics as the predicate devices. This premarket notification has described the characteristics of the MedRelief Microcurrent TENS device in sufficient detail to assure substantial equivalence.

E. TECHNOLOGICAL CHARACTERISTICS

Both new and predicate devices employ electronic circuitry to produce microcurrent output waveforms. The MedRelief is completely analog in nature--there is no software.

F. TESTING

Healthonics carried out performance testing to address the following issues:

1. Electrical Safety -- The MedRelief device meets the requirements of UL-2601;

2. Electromagnetic Compatibility -- The MedRelief device meets the applicable requirements of EN 60601-1-2;

3. Performance testing for the purposes of addressing the points in the FDA guidance document, "Guidance for TENS 510(k) Content;"

4. Conformance to the Performance Standard of ANSI/AAMI NS-4-1985.

The performance testing demonstrates that the MedRelief is substantially equivalent to the predicate devices.

G. CONCLUSIONS

In summary, this pre-market submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2001

T. Whit Athey, Ph.D.
Senior Consultant
Representing Healthonics, Inc.
C. L. McIntosh & Associates
12300 Twinbrook Parkway, Suite 625
Rockville, Maryland 20852

Re: K003507
Trade Name: MedRelief Microcurrent TENS
Regulatory Class: II
Product Code: 84 GZJ
Dated: February 5, 2001
Received: February 9, 2001

Dear Dr. Athey:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: This response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K003507

Device Name: MedRelief Microcurrent TENS

Indications For Use:

The MedRelief Microcurrent TENS device is intended for the treatment of chronic intractable pain.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

for Mark N Milhorn

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003507